Application No. 10/677,694
Docket No. IB-8 (A4-1770)
Amendment dated February 2, 2006
Reply to Office Action of November 2, 2005

Amendments to the Specification:

Please replace the two paragraphs under the section "Summary of the Invention" (starting on page 3) with the following two amended paragraphs:

The invention comprises a telemetric sensing system for monitoring physiologic parameters used to evaluate heart condition in CHF patients. The system includes an implantable sensor unit and a companion reader unit. The ~~batteryless, wireless pressure~~ sensor unit, which is preferably batteryless and wireless, is implanted in any of several locations in the heart (e.g. LA, LV, pulmonary artery (PA)). The sensor unit ~~implant~~ may be delivered percutaneously (for example, by catheter) or surgically. Once in place, the sensor unit ~~implant~~ will be wirelessly interrogated with the reader unit.

Upon placement in the respective locations in the heart, the sensor unit ~~implant~~ is capable of measuring and transmitting, in real time, any of various physiologic parameters including Left Ventricular End Diastolic Pressure (LVEDP), Left Atrium Pressure, and Mean Left Atrium Pressure (MLAP). When desired, the sensor unit ~~implant~~ is also able to monitor other parameters, including but not limited to blood flow and blood chemistry. Monitoring one or more of these

parameters gives the physician several advantages:

- Enables earlier diagnosis of a failing heart; ~~heart~~
- Facilitates earlier intervention in the course of a disease; ~~disease~~
- Enables better tailoring of medications or other treatments and therapies to maximize cardiac output while reducing LVEDP ~~LVEDP~~
- Facilitates the identification of other complications from treatments or disease progression (e.g. weakening of other heart chambers); ~~chambers)~~
- Gives faster feedback on the impact of medications and/or pacing changes on heart function; ~~function.~~
- Facilitates defibrillator or pacemaker optimization; ~~optimization~~
- Lowers overall treatment costs; ~~costs~~
- Decreases frequency and/or severity of hospitalization for CHF-related conditions through improved outpatient and home care monitoring. ~~monitoring~~
- Can be incorporated into an early warning system for serious conditions; ~~conditions~~
- Enables closed-loop medical delivery systems. ~~systems~~

Please add the following new paragraph on page 5 following the paragraph that begins "Figure 5 is a side view":

Figure 6 is a block diagram of a closed-loop pacing/ICD tuning system incorporating the magnetic telemetry-based physiologic monitoring system of the present invention.

Please replace the second paragraph under "Detailed Description of Preferred and Alternative Embodiments of the Invention" on page 5 with the following amended paragraph:

In order to provide for the effective monitoring, management, and tailoring of treatments for congestive heart failure, the present invention provides a wireless sensing system. The system comprises ~~two parts:~~ an implantable ~~pressure~~ monitor in the form of a sensor which is securely anchored in a cavity of the heart; and an external reader that may transmit ~~reader that both transmits~~ power to and receive ~~receives~~ transmitted data from the sensor. ~~implant.~~ Data transmitted from the sensor ~~implantable device~~ may include pressure, temperature, calibration data, identification data, fluid flow

rate, chemical concentration, and/or other physiologic parameters.

Please replace the paragraph bridging pages 6 and 7 with the following amended paragraph:

The ~~batteryless,~~ wireless telemetry link between the sensor and the reader is preferably implemented using either a resonant or passive, magnetically coupled scheme. A resonant device 101 (shown in Figure 2) is the simplest approach, and consists only of a packaged inductor coil 103 and capacitive pressure sensor 102. Together, the sensor 102 and coil 103 ~~two elements~~ form a circuit that has a specific resonant frequency. At that resonant frequency, the circuit presents a measurable change in magnetically coupled impedance load to an external coil 105 associated with an external reader 104. Because the resonant frequency is a function of the ~~coil~~ inductance of the coil 103 and the ~~sensor~~ capacitance of the sensor 102, as pressure changes the resonant frequency changes as well. The external ~~An external~~ reader 104 is able to determine pressure by monitoring the frequency at which the coil antenna 105 impedance changes.

Please replace the first full paragraph on page 7 with the following amended paragraph:

The preferred communication scheme for the present invention, shown in Fig. 3 as being between a passive implant device 201 and an external reader 202, is based on magnetic telemetry. Devices that have on-board circuitry but still receive their operating power from an external source (i.e., are batteryless) are referred to herein as passive. Without the external reader 202 ~~passive devices 201 (shown in Figure 3). Without an external reader~~ present, the implant device 201 lays passive and without any internal means to power itself. When a pressure reading is desired, the reader ~~device~~ 202 is brought into a suitable range to the implant device 201. In this case the external reader 202 uses an alternating magnetic field to induce a voltage in the implant device 201. When sufficient voltage has been induced in the implant device 201, a rectification circuit 203 converts the alternating voltage on the receiver coil 204 into a direct voltage that can be used by the electronics 205 as a power supply for signal conversion and communication. At this point the implant device 201 can be considered alert and, in the preferred embodiment, also ready

for commands from the reader 202. The maximum achievable distance is mostly limited by the magnetic field strength necessary to turn the implant device 201 on. This telemetry scheme has been proven and used extensively in the identification and tracking industry (e.g., implantable RF ID technology from Texas Instruments or Digital Angel) with a great deal of acceptance and success.

Please replace the paragraph bridging pages 7 and 8 with the following amended paragraph:

Once the direct voltage in the implant device 201 has been established for the circuit operation, a number of techniques may be used to convert the ~~sensor~~ output of the device 201 into a form suitable for transmission back to the reader 202. ~~device.~~ In the preferred embodiment, a capacitive pressure sensor 206 and sigma delta conversion or capacitance to frequency conversion of the sensor output may be easily used. Capacitive sensors are preferred due to the small power requirements for electronics when reading capacitance values. Many pressure sensors are based on piezoresistive effects and, while suitable for some applications, do

suffer in this application due to the higher power levels needed for readout. Sigma delta converters are preferred due to the tolerance of noisy supply voltages and manufacturing variations.

Please replace the second full paragraph on page 8 with the following amended paragraph:

In addition to the many available modulation techniques, there are many technologies developed that allow the implant device 201 to communicate back to the reader 202 the signal containing pressure information. It is understood that the reader 202 ~~device~~ may transmit either a continuous level of RF power to supply the ~~implant's~~ needed energy for the device 201, or it may pulse the power allowing temporary storage in a battery or capacitor device (not shown) within the device 201. Similarly, the implant device 201 of Fig. 3 may signal back to the reader 202 at any interval in time, delayed or instantaneous, during reader RF (Radio Frequency) transmission or alternately in the absence of reader transmission. The implant device 201 may include a single coil antenna 204 for both reception and transmission, or it may include two antennas 204 and 221, one each

for transmission ~~204~~ and reception, respectively. ~~221.~~ There are many techniques for construction of the reader coil 219 and processing electronics known to those skilled in the art. The reader 202 may interface to a display, computer, or other data logging devices 220.

Please replace the third full paragraph on page 8 with the following amended paragraph:

The electronic circuit may consist of the coil antenna 204, ~~a receiving inductor coil 204,~~ rectification circuitry 203, signal conditioning circuitry 211, and signal transmission circuitry 212.

Please replace the paragraph bridging pages 8 and 9 with the following amended paragraph:

A large number of possible geometries and structures are available for the coil 204 and are ~~receiver coil and~~ known to those skilled in the art. The coil conductor may be wound around a ferrite core to enhance magnetic properties, deposited on a flat rigid or

flexible substrate, and formed into a long/skinny or short/wide cylindrical solenoid. The conductor is preferably made at least in part with a metal of high conductivity such as copper, silver, or gold. The coil 204 ~~coil~~ may alternately be fabricated on implantable sensor substrates. Methods of fabrication of coils on the sensor substrate include but are not limited to one or more or any combination of the following techniques: sputtering, electroplating, lift-off, screen printing, and/or other suitable methods known to those skilled in the art.

Please replace the paragraph bridging pages 9 and 10 with the following amended paragraph:

The signal transmission circuitry 212 transmits the encoded signal from the signal conditioning circuitry 211 ~~circuitry~~ for reception by the external reader 202. ~~an external reader.~~ Magnetic telemetry is again used for this communication, as the transmission circuitry 212 generates an alternating electromagnetic field that propagates to the reader 202. Either the same coil 204 is used for signal reception and for transmission, or alternately the second coil 221 ~~a second coil 221~~ is dedicated for transmission only.

Please replace the first full paragraph on page 11 with the following amended paragraph:

The system may be implemented as a closed-loop pacing/ICD (Implantable Cardioverter Defibrillator) tuning system as represented in Figure 6, in which sensor data is fed to a patient pacemaker of a pacing/ICD unit 106 for tailoring of pacing/ICD function. The implanted sensor device 101/201 ~~101, 201,~~ may be directly interrogated by the pacing/ICD unit 106 (i.e. without requiring the intermediate external reader 104/202). ~~an intermediate reader unit).~~ It may also be interrogated by the pacing/ICD unit 106, but with an additional, external power unit 107 ~~unit~~ solely for transmitting power to the sensor device 101/201. ~~implant.~~ Alternatively, the sensor data may first be transmitted to an external reader 104/202 and then re-transmitted to the pacing/ICD unit 106. Finally, the system may be configured such that both an external reader 104/202 and the pacing/ICD unit 106 may interrogate and/or power the sensor device 101/201. ~~(Sonbol add claims related to this P)~~

Please replace the second full paragraph on page 13 with the following amended paragraph:

A second package option can be attached with a metal tine or barb placed with a catheter. These devices work well in <u>trabeculated</u> ~~tribeculated~~ areas of the heart, and therefore are used often for implanting pacing leads in the right ventricle. Clips or expanding probes may also be used~~,~~ both of which would penetrate the heart or vessel wall slightly.

Please delete the last full paragraph on page 13, which starts with "Devices have been made."

Please replace the paragraph in the Abstract with the amended paragraph submitted herewith on a separate sheet pursuant to 37 CFR 1.72.